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10/785,431	02/24/2004	Richard S. Sanders	GUID.048US01 (01-158)	8603

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EXAMINER	
MALAMUD, DEBORAH LESLIE	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
01/16/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/785,431

Applicant(s)

SANDERS, RICHARD S.

Examiner

Deborah Malamud

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 8-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/25/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The examiner acknowledges the amendments received 25 October 2007.

Claims 8-62 are withdrawn; claims 1-7 are pending.

### ***Claim Objections***

2. In view of the amendments received 25 October 2007, the objection to claims 8-62 and 6 are withdrawn.

### ***Response to Arguments***

3. Applicant's arguments, see "Remarks," filed 25 October 2007, with respect to the rejection(s) of claim(s) 1-7 under Duggan (U.S. 5,318,593) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hafelfinger et al (U.S. 5,003,975).

### ***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1-2, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hafelfinger et al (U.S. 5,003,975). Hafelfinger discloses (col. 4, lines 1-41; Figs. 1, 1a) "an implantable pacemaker that has electrode configuration programming capabilities, as well as, unipolar/bipolar lead interchangeability (meaning that either unipolar or

bipolar operation may be programmed, and either unipolar or bipolar leads may be inserted into the pacemaker connector block). The present invention utilizes load recognition (i.e., the load impedance presented by the lead/tissue interface during a stimulation pulse) to determine the integrity of the implanted leads and to automatically change the electrode configuration to an available and operative configuration." The examiner considers this to be an implantable housing; a first electrode coupled to the housing and a second electrode; monitoring circuitry coupled to the first and second electrodes; and energy delivery circuitry coupled to the first and second electrodes. The device includes a "special monitoring circuit within the pacemaker that performs a lead impedance measurement whenever the operating configuration of the pacemaker is programmably changed, e.g., from bipolar to unipolar or vice versa. From this measurement, a determination is made as to whether the correct impedance is present for the existing operating configuration. If the expected impedance is not measured, then a different configuration measurement is made according to a predefined sequence until a correct impedance value is measured. The occurrence of a correct measurement is then used to set the pacemaker configuration accordingly." In other words, if a unipolar lead is sensed as connected to the device, the device is programmed to disable the energy delivery circuitry used in a bipolar lead. Therefore, the examiner considers Hafelfinger to disclose a lead interface coupled to the housing; and a controller coupled to the lead interface, monitoring circuitry, and energy delivery circuitry, the controller transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry (used for a bipolar lead) is disabled, to the energy

delivery mode, in which the energy delivery mode, in which the energy delivery circuitry is enabled, at least in part in response to coupling the cardiac lead to the lead interface (since coupling the lead triggers the lead impedance sensing that determines the mode to be used by the device).

6. Regarding claim 2, Hafelfinger discloses (col. 7, lines 18-22; Fig. 2) a "sensing detector (60) is coupled to the terminal (46) to respond to sensed heart activity." The examiner considers this to be detection circuitry provided in the housing and coupled to the first and second electrodes.

7. Regarding claims 5 and 7, Hafelfinger discloses, (col. 7, lines 46-52; Fig. 3) "A configuration switch 80 is shown connected between pairs of leads (12 and 14) via connectors (82A, 82B) and the pacing stimulation and sense stage (40B). Also shown is the connection to the case (31). In conventional fashion, a control microprocessor (84) or equivalent, is coupled to control the pacer stimulation and sense stage and the configuration switch." The examiner considers this to be a mode switch coupled to the controller; and a receiver coupled to the controller.

### ***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Hafelfinger et al (U.S. 5,003,975) in view of Duggan (U.S. 5,318,593). Hafelfinger discloses the claimed invention except for a memory provided in the housing and

coupled to the detection circuitry. Duggan however discloses (col. 7, lines 51-67; Figure 1) a "pacemaker (12) includes a body tissue and fluid resistant casing (13), a first lead (17) coupled to and attached by an electrode to the heart's atrium (40), and a second lead (19) coupled to and attached by an electrode to the patient's ventricle (42).

Further, there is shown an external transmitter (10) coupled by a lead (15) to a coil or antenna (16) disposed externally of the patient's body (14), for transmitting RF coupled signals to the internally implanted pacemaker. Further, there is shown a monitor (63) coupled to the transmitter by a lead (59). As will be explained in detail, the transmitter (10) may be actuated to send signals via the lead (15) and the coil (16), to the internally implanted pacemaker (12), whereby its mode of operation may be changed from one mode to another selected mode; thus, the physician can control the type of pacing imposed upon the patient's heart in accordance with the patient's altered condition."

Duggan further discloses (col. 27, lines 8-24) "the leads could be coupled to heart tissue, other tissue or transducers, to sense the patient's EKG, pulse rate, pulse width, the time of depolarization between the atrium and ventricle, etc. The time of transmission of a depolarization signal is considered to be indicative of the heart's condition and a window is established by a sensing program in accordance with a normal transmission time. If the received signal is outside the limits of such a window, an indication thereof is transmitted externally of the pacemaker. In a data gathering mode, it is contemplated that the latches associated with the associated leads to the heart sites, tissue sites, or transducers are coupled one at a time, by selectively closing the corresponding select switch (330), whereby that data is sent by the receiver (341) to

an external monitoring device." Duggan and Hafelfinger both disclose systems for sensing cardiac activity and controlling pacemaker functions. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hafelfinger's implantable mode switch device with Duggan's implantable memory in order to store sensed signals for further diagnosis and study.

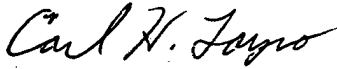
10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hafelfinger et al (U.S. 5,003,975) in view of Ideker et al (U.S. 6,205,357). Hafelfinger discloses the claimed invention except for a programmable filter coupled to the detection circuitry. Ideker however discloses (col. 7, lines 14-20) "electrodes shown in the positions illustrated panel 3A are, as shown in panel 3B, operatively connected to differential amplifiers (42, 42a, 42b, 42c), in turn connected to bandpass filters (44, 44a, 44b, 44c) and sensed event detector circuitry (46, 46a, 46b, 46c), contained in the ICD (40). Amplification and bandpass filtering are followed by sensed event detection." Hafelfinger and Ideker both disclose devices for switching between sensing and stimulating modes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hafelfinger's mode-switching and therapy-disabling system with Ideker's programmable filter in order to eliminate any noise from the sensed signal and prevent a misdiagnosis.

**Conclusion**

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**CARL LAYNO**  
PRIMARY EXAMINER

  
Deborah L. Malamud  
Patent Examiner  
Art Unit 3766